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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/643,006

08/18/2003

Eric G. Lovett

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12/08/2006

HOLLINGSWORTH & FUNK, LLC

8009 34TH AVE S.

SUITE 125

MINNEAPOLIS, MN 55425

EXAMINER

NGUYEN, HUONG Q

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/643,006

Applicant(s)

LOVETT ET AL.

Examiner

Helen Nguyen

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 May 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) 5, 8, 9, 16, 27, 36-38, 45, 53, 56, 57, 59 and 61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 10-15, 17-26, 28-35, 39-44, 46-52, 54, 55, 58, 60 and 62-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/11/2004, 3/3/2005</u>                                       | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Species 1A, 2A, 3B, 4B, 5C, 6A, and 7B in the reply filed on 5/26/2006 is acknowledged. The traversal is on the ground(s) that the species are not mutually exclusive, as demonstrated in Figure 3 (for Species 5) and Figure 6 (for Species 4).

While examiner agrees with applicant that Species 4 and 5 are not mutually exclusive, there is no evidence that Species 1-3 and 6-7 may be traversed under the same argument. In fact, there is reason to believe the restriction requirement is proper regarding Species 1-3 and 6-7 is proper because said species are distinct for reasons such as they are mutually exclusive and have different modes of operation. For example, regarding the election between Species 2, applicant discloses that one of the different sensors may be used to sense muscle tone (§0031 and 0102). Therefore, the election requirement between Species 1-3 and 5-6 is still deemed proper and is therefore made FINAL.

2. Claims 5, 8-9, 16, 27, 36-38, 45, 53, 56-57, 59, and 61 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species. Applicant timely traversed the restriction (election) requirement in the reply filed on 5/26/2006. **Claims 1-4, 6, 7, 10-15, 17-26, 28-35, 39-44, 46-52, 54, 55, 58, 60 and 62-85** remain pending.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on 3/11/2004 and 3/03/2005 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97.

Accordingly, the information disclosure statement is being considered by the examiner.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 1-4, 6-7, 10-15, 17-26, 28-35, 39-44, 46-52, 54-55, 58, 60, and 62-85** are rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al (US Pub No. 20040111040) in view of Verrier et al (US Pat No. 5902250).

6. In regard to **Claims 1-2, 6, 12-15, 31-34, 48-50, 54, 62-65, 75, and 81**, Ni et al disclose a method and apparatus comprising:

a detector system comprising sensors (101, 102) for detecting conditions related to sleep, the sleep-related conditions comprising a condition associated with sleep, such as muscle tone (§0052), and another condition associated with a sleep-wake status of a patient, such as body movement (§0052), best seen in Figure 1 (§0053);

a classification system, referred to as "sleep detector" (134, 321), for classifying one or more sleep states based on the detected conditions (§0056-0057), wherein classifying the one or more sleep states is performed at least in part implantably, as best seen in Figure 3 (§0070).

However, Ni et al do not disclose the sleep condition detected as specifically associated with REM sleep. Ni et al do disclose however the importance of taking into account REM sleep (§0003-0004).

Art Unit: 3736

7. Verrier et al disclose an analogous method and apparatus for classifying sleep comprising sensing a physiological condition associated with REM sleep (Col.11: 29-35) thereby determining if a patient is in REM sleep state (Col.8: 39-41) to gather valuable information regarding the specific sleep state to better diagnose and treat patients afflicted with conditions directly associated with REM sleep (Col.1: 25-30), whereby REM sleep can be determined from muscle tone (Col.3: 18-22). Therefore, it would have been obvious to one of ordinary skill in the art to modify the invention of Ni et al to modify the method and apparatus to detect a physiological condition associated specifically with REM sleep, to provide an improved invention that determines when a patient is in REM sleep and allows subsequent diagnostic and treatment options for conditions directly associated with REM sleep.

8. In regard to **Claims 3-4 and 51-52**, Ni et al disclose the method and apparatus for detecting the sleep-wake status of the patient by patient activity using an accelerometer (§0077).

9. In regard to **Claims 7, 35, and 55**, Ni et al disclose the method and apparatus for sensing muscle tone as well as EMG signals associated with sleep (§0052) but do not explicitly disclose using an electromyogram sensor to sense muscle tone. Therefore, it would have been obvious to sense muscle tone using an electromyogram sensor as such sensor is known to one of ordinary skill in the art as an effective means to sense muscle tone, as also suggested by the invention of Ni et al.

Art Unit: 3736

10. In regard to **Claims 10-11**, Ni et al disclose detecting the conditions related to sleep comprises detecting body posture or torso orientation (§0119).

11. In regard to **Claims 17 and 39**, Ni et al disclose the method and apparatus for classifying the one or more sleep states on a real-time basis.

12. In regard to **Claims 18-24, 40-42, 66-72, 76-79, and 82-84**, Ni et al disclose the method and apparatus for providing therapy, such as respiratory (§0041) or cardiac therapy (§0072), both of which may be preventive therapy, through various systems capable of testing therapy parameters and providing diagnostic testing, monitoring of patient conditions, and collecting data (§0050).

13. In regard to **Claims 25-26, 43-44, 80, and 85**, Ni et al disclose the method and apparatus to determine physiological intrinsic responses of the patient during sleep such as breathing (§0058).

14. In regard to **Claims 28-30, 46-47, and 73-74**, Ni et al disclose the method and apparatus for classifying the one or more sleep states adaptively comprising learning sleep-related responses of a patient wherein adjusting the determination of a sleep threshold of a patient using various sleep-related sensors constitutes as such (§0052, 0053, 0090) and then classifying the one or more sleep states using said learned sleep-related responses. Furthermore, Ni et al disclose using historical data, which constitutes changes in sleep-related signals over a period of time, to

Art Unit: 3736

establish sleep thresholds (¶0084) for subsequent sleep classification. Therefore, it would have been obvious to one of ordinary skill in the art to then detect such changes in sleep-related signals over a period of time and learning the sleep-related responses based on the detected changes to continuously update the historical data for an improved invention that takes into account current patient conditions.

15. In regard to **Claims 58 and 60**, Ni et al disclose the muscle tone sensor (101) is mechanically coupled to an implantable device, specifically a housing (390) of the implantable cardiac device, and the classification system (321) is disposed within a housing (390) of the implantable cardiac device, best seen in Figure 3.

### *Conclusion*

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Florio et al (US Pat No. 7092755) disclose a system and method of cardiac pacing for sleep apnea and Hobson et al (US Pat No. 4836219), Lavie (US Pat No. 5280791), and Martens et al (US Pat No. 5299118) all disclose a sleep classification system.

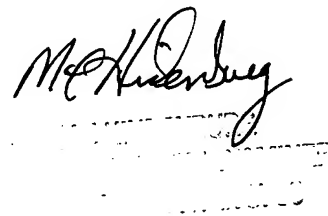
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN  
12/06/2006

A handwritten signature in black ink, appearing to be 'JW' or similar, located below the date.A handwritten signature in black ink, appearing to be 'McKenney', located above a rectangular stamp. The stamp contains some text that is mostly illegible but appears to be a date or reference number.